



Department of Neurology

CONSENT FORM

The Tolerability of Buspirone for the Treatment of Anxiety in Parkinson's Disease

Principal Investigator: Irene Richard, MD

This consent form describes a research study, what you may expect if you decide to take part and important information to help you make your decision. Please read this form carefully.

The study staff will explain this study to you. Please ask questions about anything that is not clear before you agree to participate. You may take this consent form home to think about and discuss with family or friends.

- Being in this study is voluntary – it is your choice.
- If you join this study, you can change your mind and stop at any time.
- If you choose not to take part, your routine medical care will not be changed in any way.
- There are risks from participating and you should understand what these mean to you.

Introduction

You are being asked to take part in this study because you have Parkinson's disease and anxiety.

This study is being conducted by Irene Richard, MD of the University of Rochester's Department of Neurology.

Purpose of Study

The purpose of this study is to determine if a drug called buspirone is safe when given to patients with Parkinson's disease for the treatment of anxiety. Buspirone has been approved by the Food and Drug Administration (FDA) to treat generalized anxiety disorder in the general population. However, it is investigational in this study because it is not FDA approved to treat anxiety in Parkinson's disease.

Description of Study Procedures

In this study, we are comparing buspirone to placebo (a pill that looks like the study drug but does not contain any active drug). If you are eligible and decide to take part in this study, you will be randomized to take either flexible dosage buspirone or placebo.

Randomized means that we will use a computer program to assign you by chance to either buspirone or placebo. Subjects will be randomized in a 4:1 ratio, meaning you have an 80% chance of receiving study drug and a 20% chance of receiving placebo.

Flexible dosage means that the investigator will decide, based on your response to the study drug and following certain parameters, what dosage you will take.

Neither you nor the researchers will know whether you are taking study drug or placebo.

There are at least 6 in-person visits and 2 telephone visits throughout the study.

Screening Visit

This visit will take about 2-3 hours. During this visit we will:

- Review the study, answer any questions you may have, and ask you to sign the consent form if you wish to participate in the study
- Assign a subject identification number
- Ask for the name, address, and phone number of your primary care doctor. The study team will notify this doctor of your study participation.
- Perform a general medical and neurological examination
- Review your medical history
- Review your current medication use
- Test your memory and thinking
- Obtain your heart rate, temperature, and blood pressure
- Have you complete a questionnaire about your mood
- Ask you some questions about your swallowing
- If indicated, take a blood sample to assess your liver and/or kidney function.
- If you are a woman who can get pregnant, a urine pregnancy test will be done. If you are pregnant, you will not be able to participate in this study.

Baseline Visit

This visit will take about 2-3 hours and must occur within 0 to 14 days of your Screening Visit. During this visit we will:

- Review basic information about yourself including age, sex, educational status, occupation, and marital status
- Review your health, current medication use, and any problems you may have had since your last visit
- Ask you questions about your history of Parkinson's disease, including your initial symptoms, time of diagnosis, and development of new symptoms over time
- Obtain your heart rate, temperature, and blood pressure
- Perform an assessment of your Parkinson's disease
- Have you complete several questionnaires about your Parkinson's disease symptoms and mood
- Ask you questions about your mood
- Randomize you to study drug and give you a supply of study drug. You will be given instructions on how to take the study drug. The amount of study drug you take will start low and be slowly increased. The study drug bottles should be stored at room temperature (59°- 86° F). Please do not throw out any study drug bottles, even if they are empty. All bottles (including empty bottles) should be brought with you to your visits.

Remaining Scheduled Visits

Each visit will take about 2-3 hours. During these visits we will:

- Review your health, current medication use, and any problems you may have had since your last visit
- Have you complete questionnaires about your mood, the presence of dyskinesias (involuntary movements), and how you are doing overall
- Ask you questions about your mood
- Review how you have been taking your study drug and collect study drug bottles
- Obtain your heart rate, temperature, and blood pressure
- Perform an assessment of your Parkinson's disease
- Assess whether the dosage of study drug should be changed
- Give you a supply of study drug

Telephone Visits

These telephone calls will take about 20-30 minutes. During these visits we will:

- Review your health, current medication use, and any problems you may have had since your last visit
- Ask you questions about your mood
- Assess whether the dosage of study drug should be changed

Following the telephone visits, you will be asked to pick up a supply of study drug from the study site. There is a 7-day period during which these telephone visits must occur and you must pick up the study drug within the same period.

Unscheduled Visits

During the study, if you or a study team member feel that you need to be seen for an extra visit, this will be arranged. These visits will take about 1-2 hours.

During these visits we will:

- Review your health, current medication use, and any problems you may have had since your last visit
- Perform a general examination and an assessment of your Parkinson's disease. We may also perform a complete neurological examination if indicated.
- If indicated, we will take a blood sample to assess your health
- Obtain your heart rate, temperature, and blood pressure
- Review how you have been taking your study drug
- Assess whether the dosage of study drug should be changed

Premature Termination Visit

If you decide to stop participating in the study or are withdrawn from the study, we will ask that you return for a premature termination visit. This visit will take about 2-3 hours. During this visit we will:

- Review you health, current medication use, and any problems you may have had since your last visit
- If indicated, we will take a blood sample to assess your health
- Obtain your heart rate, temperature, and blood pressure
- Peform an assessment of your Parkinson's disease
- Have you complete questionnaires about your mood, the presence of dyskinesias (involuntary movements), and how you are doing overall
- Ask you questions about your mood

- Review how you have been taking your study drug and collect study drug bottles

Results of research lab tests and information about your participation in this study will be included in your electronic health record.

Number of Subjects

About 35 people will take part in this study.

Duration of the Study

Your participation in the study will last about 12 weeks.

Important Study Information

If you are a woman who can become pregnant, you must use adequate birth control methods during the study. Adequate birth control methods include:

- surgical sterilization,
- a partner who has had a vasectomy,
- oral contraceptives,
- condom plus spermicidal cream/jelly,
- cervical cap plus spermicidal cream/jelly,
- diaphragm plus spermicidal cream/jelly,
- intrauterine device (in place for at least 3 months)
- contraceptive implant or injection
- abstinence

The study staff will discuss birth control methods with you. If you become pregnant during the study, please report this to the study staff right away. We will ask you to reduce the dosage of your study drug right away. You may continue to participate in the study off of study drug and we will follow your pregnancy to completion.

Risks of Participation

The study team will monitor you carefully for any side effects of the study drug. Buspirone may cause all, some, or none of the following side effects:

- | | |
|---------------|------------------------------|
| • Dizziness | • Lightheadedness |
| • Drowsiness | • Dry Mouth |
| • Nausea | • Numbness |
| • Headache | • Abdominal/Gastric Distress |
| • Nervousness | • Diarrhea |
| • Fatigue | • Blurred Vision |
| • Insomnia | • Depression |

- Confusion
- Anger/Hostility
- Excitement
- Decreased Concentration
- Allergic Reaction (difficulty breathing; weakness closing of throat; swelling of lips, tongue or face; hives)

Buspirone may cause worsening of Parkinson's disease motor function. There may be additional side effects that we are not aware of. It is important to report any side effects to the study staff so that we can learn more about the effects of the study drug and determine if it is necessary for you to reduce the dose or stop taking the drug. If there is a medical emergency and it is necessary to know whether you are receiving placebo or buspirone, this information will be revealed.

Your anxiety may not get better or may worsen. By choosing to participate in this study, you will not be offered other potential treatments for your anxiety that might otherwise be available in a clinic setting. You will not be allowed to start any new anti-parkinsonian, anti-anxiety, or anti-depressant medications or increase the dosage of any anti-parkinsonian, anti-anxiety, or anti-depressant medications that you are already taking for the duration of the study. You will not be allowed to start psychotherapy or stop psychotherapy if you are already participating in it for the duration of the study. If your anxiety worsens to the point that you experience an unacceptable degree of emotional distress or impairment or there is concern about your safety, you will be asked to stop participating in the study and will be immediately referred to a mental health provider for treatment.

You may feel frustrated while taking certain tests used to evaluate your memory and thinking. These tests are meant to be challenging. You will be able to take breaks as necessary. Some of the questions in the questionnaires may be upsetting or make you feel uncomfortable. You are free to stop a test at any time if you feel frustrated, embarrassed, or simply choose not to continue.

Blood draws may cause pain, redness, bruising, or infection at the site of the needle stick. Rarely, some people faint. Should the study team find any significant abnormalities on the blood tests, you will be notified so that these may be looked into further. Follow up may include referral to your primary care doctor.

The study team may be notified if you receive other health care services at URM or its Affiliates (e.g., visit to the emergency room). In addition, the following individuals may know you participated in research and may see results of lab testing conducted for this study:

- Staff at the University of Rochester Medical Center and its Affiliates (e.g., Strong Memorial Hospital, Highland Hospital, URM primary care,

- specialist physician offices) who have a reason to access your electronic health record.
- Individuals who request a copy of information from your health record for activities such as treatment or payment (e.g., medical insurance companies, worker's compensation).

Because this study involves collecting personal, identifiable information about you, there is a potential for invasion of privacy or breach in confidentiality. To minimize this risk, we will assign you a subject identification number instead of labeling the information we collect from you with your name (or medical record number). All of the information we collect will be stored in a secure manner and only study team members will have access to it.

A description of this clinical trial will be available on <http://www.ClinicalTrials.gov>, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this website at any time.

Women please note:

There are insufficient data regarding the effect of buspirone in pregnant or nursing women. Women who are pregnant or nursing will not be included in the study. Women who can get pregnant must confirm, to the best of their knowledge, that they are not pregnant or intending to become pregnant during the study. Women who can get pregnant will have a urine pregnancy test before the start of the study. If the test is positive, you will not be included in the study. Adequate birth control methods are described above. Birth control should be continued for the duration of the study. If you decide you wish to become pregnant, or if you change your method of birth control, you must notify the study team immediately. In the event of pregnancy, the study drug may involve risks to the embryo or fetus, which are currently unforeseeable. If you become pregnant during your participation in the study, the study drug will be discontinued and you may continue to be followed in the study off of study drug.

Benefits of Participation

You might not benefit from being in this research study. The study drug may improve your anxiety.

New Study Findings

If we discover anything that might make you change your mind about continuing in the study, we will let you know.

Alternatives to Participation

You do not have to participate in this study to receive treatment for your anxiety.

Sponsor Support

The University of Rochester is receiving payment from the Michael J. Fox Foundation for conducting this research study.

Costs

There will be no cost to you to participate in this study. The study drug will be provided to you free of charge.

The cost of any other medications that are considered standard of care for you and for treatment of your Parkinson's disease will be your/your insurance company's responsibility.

Payments

You will not be paid for participating in this study.

Reimbursement for Travel Expenses

You will be reimbursed for distance traveled by car to attend your study visits at a rate of \$0.54/mile. You will only be reimbursed up to a maximum amount of \$50 for each visit. Such reimbursed expenses are not taxable.

Circumstances for Dismissal

You may be withdrawn from the study drug if your medical condition changes such that staying on the study drug might risk your health or this research. If you stop the study drug, you may be asked to continue attending the study visits. The entire study could be discontinued at any time by the study sponsor or the U.S Food and Drug Administration for any reason. If the study is stopped, you will be asked to have one final study visit to ensure your safety.

Early Termination

If you choose to withdraw from the study, you will be asked to have one final study visit to ensure your safety.

Compensation for Injury

If you are directly injured by the drug that is being studied, or by the clinical procedures solely required to participate in the study, you may need to pay for treatment of your injuries, but you will not be required to pay for emergency medical treatment provided at Strong Memorial Hospital or Highland Hospital. The University may seek payment for this care from your health insurer or third parties. Decisions regarding care and compensation for any other research related injury will be made on a case-by-case basis.

Confidentiality of Records and Authorization to Use and Disclose Information for Research Purposes

The University of Rochester makes every effort to keep the information collected from you private. In order to do so, we will label study information with a study identification number instead of your name, store information in a secure manner,

and restrict access to study personnel only. Sometimes, however, researchers need to share information that may identify you with people that work for the University, regulators or the study sponsor.

If you have never received a copy of the University of Rochester Medical Center (URMC) and Affiliates Notice of Privacy Practices, please ask the investigator for one.

What information may be used and given to others?

The study doctor will get your personal and medical information. For example:

- Research records
- Records about phone calls made as part of this research
- Records about your study visits
- Past and present medical records
- Results of physical exams, laboratory tests, and questionnaires obtained in the course of this research

Who may use and give out information about you?

- The study doctor and the study staff
- URMC and Affiliates

Your information may be given to:

- The Department of Health and Human Services
- The University of Rochester
- The Michael J. Fox Foundation
- Study Monitor (the person monitoring the conduct of the study)
- URMC Labs
- The U.S Food and Drug Administration (FDA) may also need to inspect study records at some point during the study or even after it has been completed. In the event that this should occur, every effort will be made to keep identifying information about you private.

Why will this information be used and/or given to others?

- To do the research
- To study the results
- To see if the research was done right

If the results of this study are made public, information that identifies you will not be used.

What if I decide not to give permission to use and give out my health information?

Then you will not be able to be in this research study.

May I review or copy my information?
Yes, but only after the research is over.

How long will this permission be valid?
This permission will last indefinitely.

May I cancel my permission to use and disclose information?
Yes. You may cancel your permission to use and disclose your health information at any time. You do this by sending written notice to the study doctor. Upon receiving the written notice, the study team will no longer use or disclose your health information and you will not be able to stay in this study. Information that has already been gathered may need to be used and given to others for the validity of the study.

May I withdraw from the study?
Yes. If you withdraw your permission to be in the study, no new health information identifying you will be gathered after that date. Information that has already been gathered may still be used and given to others.

Is my health information protected after it has been given to others?
No. There is a risk that your information will be given to others without your permission.

Contact Persons

For more information concerning this research or if you feel that your participation has resulted in any research related injury, emotional or physical discomfort, please contact: Dr. Irene Richard at (585) 341-7500.

Please contact the University of Rochester Research Subjects Review Board at 265 Crittenden Blvd., CU 420628, Rochester, NY 14642, Telephone (585) 276-0005 or (877) 449-4441 for the following reasons:

- You wish to talk to someone other than the research staff about your rights as a research subject;
- To voice concerns about the research;
- To provide input concerning the research process;
- In the event the study staff could not be reached.

Voluntary Participation

Taking part in this study is voluntary. You are free not to take part or to withdraw at any time, for whatever reason. No matter what decision you make, there will be no penalty or loss of benefit to which you are entitled. If you do choose to withdraw from the study, you will be asked to have a final visit. In the event that you do withdraw from this study, the information you have already provided will be kept in a confidential manner.

SIGNATURE/DATES

Consent for Follow-Up Contact

We would like permission to contact you annually to update your contact information. We may contact you in the future should we decide that it is important to continue following your progress or if we open a new study to follow-up on people who take part in this study. Any new studies would go through ethics review (just like this one) and would have a new consent form for you to sign. You can decide at that time whether or not you would like to participate in any additional studies.

Please check **Yes** or **No** to indicate your preference:

- Yes**, I give my consent to be contacted in the future about future studies.
- No**, I do not want to be contacted in the future.

Subject Consent

I have read (or have had read to me) the contents of this consent form and have been encouraged to ask questions. I have received answers to my questions. I agree to participate in this study. I have received (or will receive) a signed copy of this form for my records and future reference.

Subject Name (Printed by Subject)

Signature of Subject

Date

Person Obtaining Consent

I have read this form to the subject and/or the subject has read this form. I will provide the subject with a signed copy of this consent form. An explanation of the research was given and questions from the subject were solicited and answered to the subject's satisfaction. In my judgment, the subject has demonstrated comprehension of the information. I have given the subject adequate opportunity to read the consent before signing.

Name and Title (Print)

Signature of Person Obtaining Consent

Date

